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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,330	Applicant(s) CHEN ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8-10,12-17,19-22 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-10,12-17,19-22 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. .

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Amendment filed April 17, 2003, paper no. 13, has been entered.

Claims 5, 7, 11, 18 and 24 are cancelled.

Claims 1, 6, 8-10, 12-15, 19-20, 22 and 25 are newly amended.

Claims 1-4, 6, 8-10, 12-17, 19-22 and 25 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-2, 6, 8-10, 12-15, 19-22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed December 17, 2002.

Applicant's arguments filed April 17, 2003, have been fully considered but they are not persuasive.

Applicant argues that the Office appears to improperly impose an *ipsis verbis* requirement for written description. Applicant additionally argues that since the claims are drawn to plants or cells, and not the transgenes themselves, the Lily rule for sequences or chemical formulas does not apply to claims. Applicant further argues that the specification provides ample guidance in the form of examples of sequences which are known in the art, as

well as a functional description of the encoded enzyme activity. Applicant also points out that guidance for making exemplary plants comprising the betaine aldehyhde dehydrogenase transgene are disclosed. Applicant additionally points out that examples of glycine betaine biosynthetic enzymes from plant and microbial sources are known in the art (reply pages 12-15).

The Office does not impose an *ipsis verbis* requirement for written description, but does require the disclosure of a representative number of species. Additionally, the Office maintains that the Lily rule for sequences or chemical formulas does apply to claims directed to plants and cells comprising transgenes, as the transgenes serve to distinguish the transgenic plants and cells from plants and cells that occur naturally. Furthermore, the Office does not dispute that examples of sequences encoding glycine betaine biosynthetic enzymes are known in the art, but maintains that the existence of such prior art sequences alone does not support the description of the claimed genus because the effect of expressing such sequences in transgenic turfgrass is not known or disclosed.

Claims 4 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed December 17, 2002.

Applicant's arguments filed April 17, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is improper because the specification provides an adequate description of a method for making the claimed plasmid (reply page 15).

The disclosure in the specification for making the claimed plasmid does not overcome the rejection because the methods used to make the claimed plasmid cannot be relied upon to obtain the exact same plasmid in each occurrence of making the plasmid.

Claims 1-2, 6, 8-10, 12-15, 19-22 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for salt and drought tolerant transgenic turfgrass cells and plants comprising the exemplified transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis*, does not reasonably provide enablement for other salt and drought tolerant transgenic plants comprising other transgenes, for the reasons of record set forth in the office action mailed December 17, 2002.

Applicant's arguments filed April 17, 2003, have been fully considered but they are not persuasive.

Applicant argues that claims to transgenes other than the exemplified transgene encoding betaine aldehyde dehydrogenase from *Atriplex hortensis* are enabled because the synthesis of glycine betaine by various enzymes is necessarily similar. Applicant points out that the specification also discusses other enzymes which are interchangeable, and argues that the Office cites no reference to support its contention regarding unknown and undisclosed characteristics of such enzymes from nonexemplified sources. Applicant argues that the cited reference of Rathinasabapthi supports the idea that glycine betaine biosynthesizing enzymes from various sources are capable of expression in plants for the desired purpose. Applicant also argues that the specification gives several different examples of the genus of glycine betaine biosynthetic enzymes, and points out that others are known in the art. Applicant additionally asserts that only routine experimentation would be required to practice the claimed invention, as the specification

provide adequate information with respect to the process of making and using transgenic turfgrass plants and cells (reply pages 16-19).

While the synthesis of glycine betaine by various enzymes is necessarily similar insofar as the substrates and products of those enzymes are concerned, the Office maintains that the use of any glycine betaine biosynthetic enzyme obtained from any source for the purpose of making salt or drought tolerant turfgrass would be unpredictable, given the structural and functional differences between like enzymes obtained from divergent species of organisms. With respect to evidence of differences between glycine betaine biosynthetic enzymes obtained from nonexemplified sources, the Office points to the previously cited reference of Weretilnyk et al. (Archives of Biochemistry and Biophysics, Vol. 271, No. 1, May 15, pages 56-63, Applicant's IDS, see page 62 column 1 second full paragraph). With respect to the amount of experimentation required to practice the claimed invention, the Office maintains that it would require undue experimentation to practice the claimed invention because the specification does not provide sufficient guidance for one skilled in the art to select from among the numerous nonexemplified glycine betaine biosynthetic enzyme transgenes those transgenes that would be useful for the purpose of making turfgrass salt or drought tolerant, because the ability of a transgene encoding a glycine betaine biosynthetic enzyme in general or a betaine aldehyde dehydrogenase in particular to confer salt or drought tolerance on a transgenic plant is unpredictable.

Claims 1, 9 and 14, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "salt tolerant", for the reasons of record set forth in the office action mailed December 17, 2002.

Claims 13 and 21, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "drought tolerant", for the reasons of record set forth in the office action mailed December 17, 2002.

Applicant's arguments filed April 17, 2003, have been fully considered but they are not persuasive.

Applicant argues that the claims as amended are clear to one of skill in the art, and that terms such as tolerant, tolerance, resistant and resistance are commonly used in reference to stress responses. Applicant also points to pages 4-5 of the specification as defining tolerant. Applicant additionally points out that the PTO regularly issues patents with such terms in the claims (reply page 4).

The rejection is maintained because it is unclear what the comparative basis for tolerance is. It is unclear whether the claimed cells and plants are tolerant relative to nontransformed turfgrass cells and plants as a consequence of the expression of the transgene, or whether the claimed cells and plants are tolerant relative to non-turfgrass cells and plants as a consequence of some factor other than the transgene. Additionally, the definition of "tolerant" set forth in the specification does not limit the term "tolerant" in the claims. Furthermore, with respect to the use of "tolerant" in the claims of other patents, no term is per se definite. Each application is examined on its own merits according to the applicable standards, and a given term may or may not be indefinite depending on the context of each particular application.

Claims 10 and 22, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "A transgenic seed". While claim 10 is drawn to "A transgenic seed" produced from the transgenic plant of claim 9, and claim 22 is drawn to "A transgenic seed" produced from the transgenic plant of claim 14, it is unclear what

transgene(s) the seed is transgenic for, because the seed could be transgenic for a variety of transgenes other than the transgene possessed by the parent plant. It is suggested that the claims be amended to indicate the identity of the transgenic that the seed is transgenic for.

Claim Rejections - 35 USC § 103

Claims 1-2, 6, 8-10, 12-15, 19-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rathinasabapthi et al. (Planta, 1994, Vol. 193, pages 155-162) in view of Hartman et al. (Bio/Technology, September 1994, Vol. 12, pages 919-923, Applicant's IDS), and Marcum (J. Amer. Soc. Hort. Sci., 1994, Vol. 119, No. 4, pages 779-784, Applicant's IDS), for the reasons of record set forth in the office action mailed December 17, 2002. Xiao et al. is no longer relied upon.

Applicant's arguments filed April 17, 2003, have been fully considered but they are not persuasive.

Applicant argues that Rathinasabapthi does not teach transgenic turfgrass cells or plants, or whether plants containing the transgene are resistant or tolerant of osmotic stress. Applicant also argues that Rathinasabapthi teaches away from the present invention in teaching the importance of avoiding betaine aldehyde toxicity. Applicant additionally argues that the teachings of Hartman do not cure the deficiencies of Rathinasabapthi, as Hartman teaches that making transgenic turfgrass is unpredictable due to various technical difficulties encountered during the process. Applicant further argues that Marcum does not cure the deficiencies of Rathinasabapthi and Hartman, as Marcum teaches that glycine betaine accumulates sufficiently in turfgrass absent the expression of glycine betaine biosynthetic enzymes (reply pages 9-12).

With respect to the teachings of Rathinasabapthi, the Office acknowledges that Rathinasabapthi does not teach transgenic turfgrass cells or plants, or whether plants containing the transgene are resistant or tolerant of osmotic stress. The Office maintains, however, that the claims require only that the transgenic turfgrass cells and plants comprise a transgene encoding a glycine betaine biosynthetic enzyme, as do the transgenic plants and cells taught by Rathinasabapthi. The Office also disagrees that Rathinasabapthi teaches away from the present invention in teaching the importance of avoiding betaine aldehyde toxicity. Rathinasabapthi also teaches that because nontransgenic tobacco plants do not naturally accumulate glycine betaine, they lack both choline monooxygenase, which produces betaine aldehyde from choline, and betaine aldehyde dehydrogenase, which converts betaine aldehyde to glycine betaine (page 155). Since nontransgenic tobacco plants do not produce betaine aldehyde dehydrogenase endogenously, tobacco plants transgenic for a choline monooxygenase transgene could accumulate betaine aldehyde at levels toxic to the plant. The issue of betaine aldehyde toxicity is less significant for transgenic turfgrass cells and plants comprising a glycine betaine biosynthetic enzyme transgene such as choline monooxygenase, as nontransgenic turfgrass cells and plants were known in the art to accumulate glycine betaine, and would thus already have an endogenous supply of betaine aldehyde dehydrogenase to convert betaine aldehyde to glycine betaine.

With respect to the teachings of Hartman, the Office maintains that it would be within the abilities of one skilled in the art to address the technical difficulties encountered during the process of making transgenic turfgrass. The Office also notes that the specification teaches at page 12 lines 26-30 that "The transgenic plants of the present invention may be made by

following transformation/regeneration protocol, based on biolistic delivery of transforming DNA according to the method of Hartman et al. (1994, Bio/Technology 12:919-923)."

With respect to the teachings of Marcum, that Marcum teaches that glycine betaine accumulates sufficiently in turfgrass absent the expression of glycine betaine biosynthetic enzymes does not render the claimed invention nonobvious. First, Marcum teaches that glycine betaine accumulates sufficiently for cytoplasmic osmotic adjustment in nontransgenic turfgrass in response to the salinity levels tested. Second, the preexisting ability of the plant transformed to accumulate glycine betaine teaches toward the claimed invention because it demonstrates the presence of additional substrates, enzymes and products that would be required by the product of the transgene to produce the desired effect.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Claims 3-4 and 16-17 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest turfgrass transformed with the *Atriplex hortensis* betaine aldehyde dehydrogenase gene.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 27, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638